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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,727	05/03/2001	Vincent Jen-Jr. Gau	5876P002	8418

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EXAMINER

TRAN, MY CHAU T

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 03/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/848,727	Applicant(s) GAU, VINCENT JEN-JR.	
	Examiner MY-CHAU T TRAN	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20,51,52 and 75-82 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20,51,52 and 75-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/12/04 has been entered.

Status of Claims

2. Applicant's amendment filed 11/13/03 is acknowledged and entered. Claims 53-74 have been canceled. Claims 75-82 have been added.

3. Claims 21-50 are canceled by the amendment filed on 5/5/03. Furthermore, it is noted that applicant did not include claims 21-50 in the listing of claims or their status.

4. Claims 1-20, 51-52, and 75-82 are pending.

5. This application claims priority to a provisional application 60/201,603 filed 5/3/2000.

Drawings

6. The replacement drawings were received on 11/17/03. These drawings are acceptable.

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Withdrawn Rejections

7. In view of applicant's arguments, the rejection of claims 1-9, 11-13, and 51-52 under 35 USC 102(b) as anticipated by Cozzette et al. (US Patent 5,200,051) has been withdrawn.
8. In view of applicant's arguments, the rejection of claims 1-2 and 10 under 35 USC 103(a) as being unpatentable over Cozzette et al. (US Patent 5,200,051) in view of Heller et al. (US Patent 5,403,700) has been withdrawn.
9. In view of applicant's arguments, the rejection of claims 1-2 and 14-20 under 35 USC 103(a) as being unpatentable over Cozzette et al. (US Patent 5,200,051) in view of Han et al. (US Patent 6,268,161 B1) has been withdrawn.
10. Claims 1-20, 51-52, and 75-82 are treated on the merit in this Office Action.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claim 75 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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The recitation of 'each of the electrodes is constructed of the same materials' claimed in claim 75, have no clear support in the specification and the claims as originally filed.

Furthermore, applicant did not direct where such support can be found. The specification in pages 13-14 disclosed that the counter electrode can be made of inert materials such as noble metals or carbon/graphite (paragraph [076], lines 2-3) and the reference electrode is a single layer of gold electrode (paragraph [077], lines 6-7) is not support for the claimed limitation.

Because the narrow limitation of the specification recites that each type of electrode is constructed with different materials, this is not support the broad limitation of the claim, which recites that all the electrodes (e.g. counter, reference, and working electrodes) are constructed of the same materials. Therefore, the scope of the invention as originally disclosed in the specification would not encompass the scope of the claimed limitation.

If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

13. Claim 77 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The recitation of 'each of the electrodes has a different shape' claimed in claim 77, have no clear support in the specification and the claims as originally filed. Furthermore, applicant did not direct where such support can be found. The specification in page 22 disclosed that the reaction well control the shape of the reagent (paragraph [0110], lines 1-2) is not support for the

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claimed limitation. Because the limitation of the specification recites that the shape of the reagent is control by the well “shape”, this is not support the claimed limitation, which recites that each electrodes has a different shape. Therefore, the scope of the invention as originally disclosed in the specification would not encompass the scope of the claimed limitation.

If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

14. Claim 80 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The recitation of ‘each of the at least two electrically conductive electrodes is exposed to the atmosphere before the sample reagent is contacted with the sample reagent’ claimed in claim 80, have no clear support in the specification and the claims as originally filed. Furthermore, applicant did not direct where such support can be found. The specification in page 27 disclosed that the sensor surface is not modified and is ready to use after the post fabrication cleaning (paragraph [0127], lines 3-4) is not support for the claimed limitation. Because the limitation of the specification recites that the sensor surface is clean after the post fabrication, this is not support the claimed limitation, which recites that the electrode is exposed to the atmosphere before contact with the sample reagent. Therefore, the scope of the invention as originally disclosed in the specification would not encompass the scope of the claimed limitation.

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If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

16. Claims 1-13, 15-18, 20, 51-52, 75-76, and 78-79 are rejected under 35 U.S.C. 102(b) as being anticipated by Song et al. (US Patent 5,567,302).

The presently claimed method comprises the steps of a) contacting the sample reagent with the biosensor; b) containing the sample reagent in contact with the conducting electrodes; c) measuring the electrical signal; d) determining the presence and/or quantity of the target analyte

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in the sample reagent. Additionally, the biosensor comprises a) a substrate and b) two conductive electrodes that consist of a single layer of material.

Song et al. disclose an analytical system and method for detecting biochemical agents that catalyze a redox potential change (Abstract; col. 1, lines 8-10; col. 2, lines 41-58). The method comprises the step of 1) electrochemically contacting the electrolyte containing the biochemical agent (target analyte) with the electrodes, which is in a microvolume chamber (claim 1(a); col. 8, line 51 to col. 9, line 21; col. 15, lines 10-14) (refers to the contacting and containing steps); 2) measuring the change in the potential of the electrolyte (claim 1(b); col. 2, lines 50-51; col. 8, lines 16-48; col. 15, lines 10-14) (refers to the measuring step); 3) detecting the presence of the enzymes (col. 3, lines 1-7; col. 8, lines 16-48) (refers to the determining step). The analytical system comprises a small volume detection chamber (well) (col. 1, lines 31-32; col. 17, lines 31-33; fig. 1, ref. #81-88), and an electrode array with eight electrodes sites (col. 5, line 67 to col. 6, line 10). The electrode array comprises of a silicon wafer (substrate) (col. 15, line 61), gold electrodes (single layer of conductive material), chromium as the adhesion layer (col. 16, line 30-42), and electrode leads (col. 6, lines 7-9). Therefore, the analytical system and method of Song et al. anticipate the presently claimed invention.

17. Claims 1-9, 11-13, 15-18, 20, 51-52, 75-76, and 78-82 are rejected under 35 U.S.C. 102(b) as being anticipated by Heller et al. (US Patent 5,632,957).

The presently claimed method comprises the steps of a) contacting the sample reagent with the biosensor; b) containing the sample reagent in contact with the conducting electrodes; c) measuring the electrical signal; d) determining the presence and/or quantity of the target analyte

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in the sample reagent. Additionally, the biosensor comprises a) a substrate and b) two conductive electrodes that consist of a single layer of material.

Heller et al. disclose a self-addressable self-assembling microelectronic device that can carry out a variety of reactions in microformats (Abstract; col. 4, lines 48-59; col. 5, lines 3-37). The reaction steps comprise transporting the analytes to specific location wherein the analytes are effectively concentrated and reacted with the specific binding entity at the microlocation (col. 5, lines 4-8; col. 8, lines 18-25) (refers to the contacting and containing steps), and detecting the analyte by the detectable signal (col. 9, lines 5-28; col. 19, lines 15-41) (refers to the measuring and determining steps). The microelectronic device comprises a substrate supporting an array of electronically addressable microlocations (col. 7, line 66 to col. 8, lines 4; fig. 2A) and contact pads (refers to claim 52) (col. 9, lines 52-64; fig. 3). The microlocations comprise an electrode layer, a permeation layer, and an attachment layer (col. 8, lines 1-17; fig. 2). The electrode layer comprises a metal layer such as gold (single layer of conductive material) and an adhesive layer such as titanium between the metal layer and the silicon substrate (col. 16, lines 30-41; col. 17, lines 11-21). Therefore the microelectronic device and method of Heller et al. anticipate the presently claimed invention.

18. Claims 1-8, 11-13, 15-17, 20, 51-52, and 75-82 are rejected under 35 U.S.C. 102(e) as being anticipated by Heller et al. (US Patent 6,238,624 B1; filing date 10/4/1996).

The presently claimed method comprises the steps of a) contacting the sample reagent with the biosensor; b) containing the sample reagent in contact with the conducting electrodes; c) measuring the electrical signal; d) determining the presence and/or quantity of the target analyte

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in the sample reagent. Additionally, the biosensor comprises a) a substrate and b) two conductive electrodes that consist of a single layer of material.

Heller et al. disclose a self-addressable self-assembling microelectronic device that can carry out a variety of reactions in microformats (Abstract; col. 5, lines 33-44; col. 5, lines 3-37). The reaction steps comprise transporting the analytes to specific location wherein the analytes are effectively concentrated and reacted with the specific binding entity at the microlocation (col. 5, lines 55-65) (refers to the contacting and containing steps), and detecting the analyte by the detectable signal (col. 6, lines 36-42) (refers to the measuring and determining steps). The microelectronic device comprises a substrate supporting an array of electronically addressable microlocations (col. 7, line 8-25; fig. 1 and 2) and contact pads (refers to claim 52) (col. 14, line 56 to col. 15, line 22; fig. 3). The electrode layer comprises a metal layer such as gold (single layer of conductive material) and an adhesive layer between the metal layer and the silicon substrate (col. 15, lines 32-52). Additionally, the microlocations can be any shape (col. 12, lines 31-39). Therefore the microelectronic device and method of Heller et al. anticipate the presently claimed invention.

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

21. Claims 1-20, 51-52, and 75-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Song et al. (US Patent 5,567,302) and Han et al. (US Patent 6,268,161 B1).

The presently claimed method comprises the steps of a) contacting the sample reagent with the biosensor; b) containing the sample reagent in contact with the conducting electrodes; c) measuring the electrical signal; d) determining the presence and/or quantity of the target analyte in the sample reagent. Additionally, the biosensor comprises a) a substrate and b) two conductive electrodes that consist of a single layer of material.

Song et al. disclose an analytical system and method for detecting biochemical agents that catalyze a redox potential change (Abstract; col. 1, lines 8-10; col. 2, lines 41-58). The method comprises the step of 1) electrochemically contacting the electrolyte containing the biochemical agent (target analyte) with the electrodes, which is in a microvolume chamber (claim 1(a); col. 8, line 51 to col. 9, line 21; col. 15, lines 10-14) (refers to the contacting and containing steps); 2) measuring the change in the potential of the electrolyte (claim 1(b); col. 2, lines 50-51; col. 8, lines 16-48; col. 15, lines 10-14) (refers to the measuring step); 3) detecting

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the presence of the enzymes (col. 3, lines 1-7; col. 8, lines 16-48) (refers to the determining step).

The analytical system comprises a small volume detection chamber (well) (col. 1, lines 31-32; col. 17, lines 31-33; fig. 1, ref. #81-88), and an electrode array with eight electrodes sites (col. 5, line 67 to col. 6, line 10). The electrode array comprises of a silicon wafer (substrate) (col. 15, line 61), gold electrodes (single layer of conductive material), chromium as the adhesion layer (col. 16, line 30-42), and electrode leads (col. 6, lines 7-9).

The method of Song et al. does not expressly include the calibration step comprising calibration solution and obtaining a signal.

Han et al. disclosed a biosensor for measuring the concentration of organic molecules in a solution (col. 1, lines 16-17). Han et al. claim a method of using the biosensor that included a calibration step (Han: col. 16, claim 20). The claim method step includes a control solution (calibration solution) and obtaining a signal.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the calibration step comprising calibration solution and obtaining a signal as taught by Han et al. in the method of Song et al. One of ordinary skill in the art would have been motivated to include the calibration step comprising calibration solution and obtaining a signal in the method of Song et al. for the advantage of determining the performance of the electrode before the analysis of the sample since both Song et al. and Han et al. disclose a method of measuring the concentration of the organic molecules in a solution (Song: col. 1, lines 8-10; Han col. 1, lines 16-17). Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the method combination of Song et al. and Han et al. because the calibration step is necessary to ensure the working order of the electrode.

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22. Claims 1-9, 11-20, 51-52, and 75-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al. (US Patent 5,632,957) and Han et al. (US Patent 6,268,161 B1).

The presently claimed method comprises the steps of a) contacting the sample reagent with the biosensor; b) containing the sample reagent in contact with the conducting electrodes; c) measuring the electrical signal; d) determining the presence and/or quantity of the target analyte in the sample reagent. Additionally, the biosensor comprises a) a substrate and b) two conductive electrodes that consist of a single layer of material.

Heller et al. disclose a self-addressable self-assembling microelectronic device that can carry out a variety of reactions in microformats (Abstract; col. 4, lines 48-59; col. 5, lines 3-37). The reaction steps comprise transporting the analytes to specific location wherein the analytes are effectively concentrated and reacted with the specific binding entity at the microlocation (col. 5, lines 4-8; col. 8, lines 18-25) (refers to the contacting and containing steps), and detecting the analyte by the detectable signal (col. 9, lines 5-28; col. 19, lines 15-41) (refers to the measuring and determining steps). The microelectronic device comprises a substrate supporting an array of electronically addressable microlocations (col. 7, line 66 to col. 8, lines 4; fig. 2A) and contact pads (refers to claim 52) (col. 9, lines 52-64; fig. 3). The microlocations comprise an electrode layer, a permeation layer, and an attachment layer (col. 8, lines 1-17; fig. 2). The electrode layer comprises a metal layer such as gold (single layer of conductive material) and an adhesive layer such as titanium between the metal layer and the silicon substrate (col. 16, lines 30-41; col. 17, lines 11-21).

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The method of Heller et al. does not expressly include the calibration step comprising calibration solution and obtaining a signal.

Han et al. disclosed a biosensor for measuring the concentration of organic molecules in a solution (col. 1, lines 16-17). Han et al. claim a method of using the biosensor that included a calibration step (Han: col. 16, claim 20). The claim method step includes a control solution (calibration solution) and obtaining a signal.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to as taught by Han et al. in the method of Heller et al. One of ordinary skill in the art would have been motivated to include the calibration step comprising calibration solution and obtaining a signal in the method of Heller et al. for the advantage of determining the performance of the electrode before the analysis of the sample since both Heller et al. and Han et al. disclose a method of measuring the concentration of the organic molecules in a solution (Heller: col. 5, lines 4-8; Han col. 1, lines 16-17). Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the method combination of Heller et al. and Han et al. because the calibration step is necessary to ensure the working order of the electrode.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MY-CHAU T TRAN whose telephone number is 571-272-0810. The examiner can normally be reached on Mon.: 8:00-2:30; Tues.-Thurs.: 7:30-5:00; Fri.: 8:00-3:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANDREW WANG can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct

March 25, 2004


PADMASHRI PONNALURI
PRIMARY EXAMINER